IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION
No. 5:22-CV-223-D

MELISSA MAE WATTERS, Plaintiff, v. COOPERSURGICAL, INC., et al., Defendants.	)	**ORDER**

On June 2, 2022, Melissa Mae Watters ("plaintiff" or "Watters") filed a complaint in this court alleging three claims under North Carolina law (i.e., products liability, negligence, and violations of North Carolina's Unfair and Deceptive Trade Practices Act ("UDTPA")) against defendants CooperSurgical, Inc. ("CSI"), The Cooper Companies, Inc. ("TCC"), Femcare LTD ("Femcare"), and Utah Medical Products, Inc. ("UTMD") (collectively, "defendants") [D.E. 1]. On August 23, 2022, defendants CSI, TCC, and UTMD moved to dismiss [D.E. 18] and filed a memorandum in support [D.E. 19]. On September 13, 2022, Watters responded in opposition [D.E. 23]. On September 27, 2022, CSI, TCC, and UTMD replied [D.E. 24].

On December 2, 2022, Femcare moved to dismiss due to lack of personal jurisdiction and failure to state a claim [D.E. 25] and filed a memorandum in support [D.E. 26]. On January 12, 2023, Watters responded in opposition [D.E. 31]. On February 9, 2023, Femcare replied [D.E. 34].

As explained below, the court grants TCC, UTMD, and Femcare's motion to dismiss for lack of personal jurisdiction. The court also grants TCC, UTMD, CSI, and Femcare's motion to dismiss for failure to state a claim. The court dismisses the complaint without prejudice.

I.

This complaint arises from alleged defects in Filshie Clip ("clip") medical devices, which are titanium clips with a silicon rubber lining. See Compl. [D.E. 1] ¶ 20. Doctors use the clips for laparoscopic tubal ligation. See id. In this procedure, the clip forces the fallopian tube to become necrotic and decrease in size by latching on and applying consistent pressure. See id. at ¶ 21.

Femcare, the clip manufacturer, sought and obtained conditional Premarket Approval ("PMA") by the Food and Drug Administration ("FDA"). See id. at ¶ 24. The FDA classifies the clips as "Class III" medical devices. This classification means that the clips "present a potential unreasonable risk of illness or injury[.]" Id. at ¶ 25; see 21 U.S.C. § 360(c)(1)(c). Because the clips are Class III medical devices, the FDA only authorized the clips for commercial distribution on the condition that the FDA finds that there is a "reasonable measure" of the device's safety and effectiveness. See id. at ¶ 27. Following conditional approval from the FDA in 1996, Femcare allegedly began marketing and selling the clips in the United States, including in North Carolina. See id. at ¶¶ 42–43.

During the FDA's study of the clips, defendants were responsible for providing the FDA with occasional safety updates regarding the product's performance. See id. at ¶ 47. Allegedly, the clips sometimes "migrate" while in position on the fallopian tube, which could cause significant injury and health risks. See id. at ¶ 45. Defendants allegedly underreported data to the FDA about the frequency of clip migration and the associated health risks. See id. at ¶ 51. Despite knowing the risks of clip migration, defendants allegedly continued to "tout the benefits of the [clip] over other available procedures." Id. at ¶ 52.

In April 2013, Watters underwent a tubal ligation procedure using clips allegedly "manufactured, designed, and/or distributed by Defendants." Id. at ¶¶ 56–57. The disclosure and

consent form Watters read before the procedure allegedly did not contain warnings about the risk of clip migration or its potential side effects, and Watters's healthcare providers did not know of the risk. See id. at ¶ 58. In February 2022, after Watters reported suffering from sharp pains and cramping, doctors discovered that Watters's clip had migrated. See id. at ¶ 62. Watters alleges that defendants had evidence of the clips' "propensity to migrate" but failed to warn the FDA, physicians, or patients of the damages stemming from clip migration. Id. at ¶ 67.

II.

Defendants TCC, UTMD, and Femcare move to dismiss for lack of personal jurisdiction. The court does not have personal jurisdiction over a nonresident defendant unless jurisdiction comports with North Carolina's long-arm statute and the Fourteenth Amendment's Due Process Clause. See, e.g., Mitrano v. Hawes, 377 F.3d 402, 406 (4th Cir. 2004). North Carolina's long-arm statute extends personal jurisdiction over nonresident defendants consistent with the Fourteenth Amendment's Due Process Clause. See Christian Sci. Bd. of Dirs. v. Nolan, 259 F.3d 209, 215 (4th Cir. 2001). Thus, the statutory inquiry merges with the constitutional inquiry. See id.; Atl. Corp. of Wilmington, Inc. v. TBG Tech Co., 565 F. Supp. 3d 748, 759 (E.D.N.C. 2021).

Due process requires a defendant to have "certain minimum contacts with the forum such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice." Helicopteros Nacionales de Colom., S.A. v. Hall, 466 U.S. 408, 414 (1984) (alteration and quotations omitted). The minimum contacts analysis focuses on whether a defendant "purposefully directed his activities at residents of the forum" and whether the causes of action arise out of or relate to those activities. Burger King Corp. v. Rudzewicz, 471 U.S. 462, 472 (1985) (quotation omitted); see Ford Motor Co. v. Mont. Eighth Jud. Dist. Ct., 141 S. Ct. 1017, 1024–25 (2021). The analysis ensures that a defendant is not haled into a jurisdiction's court "solely as a result of random,

fortuitous, or attenuated contacts." Burger King, 471 U.S. at 475 (quotations omitted); see Ford Motor Co., 141 S. Ct. at 1025. The analysis focuses "on the relationship among the defendant, the forum, and the litigation." Walden v. Fiore, 571 U.S. 277, 284 (2014) (quotation omitted); see Ford Motor Co., 141 S. Ct. at 1024–25; Bristol-Myers Squibb Co. v. Superior Ct., 137 S. Ct. 1773, 1781 (2017).

The extent of the contacts needed for jurisdiction turns on whether the claims asserted against a defendant relate to or arise out of the defendant's contacts with the forum state. See Ford Motor Co., 141 S. Ct. at 1025; Bristol-Myers Squibb, 137 S. Ct. at 1780; ALS Scan, Inc. v. Dig. Serv. Consultants, Inc., 293 F.3d 707, 712 (4th Cir. 2002). If the defendant's contacts with the state are the basis for the suit, specific jurisdiction may exist. ALS Scan, 293 F.3d at 712. In determining specific jurisdiction, the court considers: "(1) the extent to which the defendant purposefully availed itself of the privilege of conducting activities in the State; (2) whether the plaintiffs' claims arise out of those activities directed at the State; and (3) whether the exercise of personal jurisdiction would be constitutionally reasonable." Id. (alteration and quotations omitted). Thus, the "constitutional touchstone" of specific personal jurisdiction "remains whether the defendant purposefully established minimum contacts in the forum State." Burger King Corp., 471 U.S. at 474 (quotation omitted); see Bristol-Myers Squibb, 137 S. Ct. at 1781–82; Walden, 571 U.S. at 284–91.

III.

Watters concedes that this court lacks general jurisdiction over TCC, UTMD, and Femcare. Watters, however, argues TCC, UTMD, and Femcare are subject to specific jurisdiction. As for TCC and UTMD, Watters argues that these defendants marketed and distributed the clips in North Carolina and thereby created specific jurisdiction in North Carolina. [D.E. 23] 16–27. TCC and UTMD respond that they had nothing to do with the clips used in Watters's April 2013 surgery and

cite affidavits confirming that UTMD and TCC were not marketing clips in April 2013 when Watters underwent her initial surgery. See [D.E. 19-1, 19-2]; [D.E. 24] 2–4.

Watters does not dispute the underlying facts in the UTMD and TCC affidavits. See [D.E. 23]. Nonetheless, Watters contends that UTMD's affidavit admits sufficient minimum contacts with North Carolina. See [D.E. 23] 17–21. Specifically, because the affidavit admits that UTMD has engaged in activities in North Carolina since 2019, Watters argues that UTMD purposefully availed itself of conducting activities in North Carolina. See id. Essentially, Watters argues that UTMD's market participation in North Carolina since 2019 exposes it to personal jurisdiction in North Carolina for the April 2013 surgery. See id.

Watters's argument ignores that the facts establishing personal jurisdiction must be tied to the same underlying controversy that gave rise to the lawsuit. See Bristol-Myers Squibb, 137 S. Ct. at 1780 (holding that contacts not creating "the very controversy that establishes jurisdiction" are not sufficient to establish personal jurisdiction); Goodyear Dunlop Tires Operations, S.A. v. Brown, 564 U.S. 915, 931 n.6 (2011) ("[E]ven regularly occurring sales of a product in a State do not justify the exercise of jurisdiction over a claim unrelated to those sales."); Burger King, 471 U.S. at 472–73 (holding that the "fair warning" requirement of the Due Process Clause is only satisfied if the litigation "arise[s] out of or relate[s] to" the activity defendant directed toward the forum). Watters's injury does not arise out of or relate to UTMD's post-2019 North Carolina market participation. Therefore, this court lacks personal jurisdiction over UTMD.

Alternatively, Watters suggests that the relevant date for personal jurisdiction in this case is 2022, when Watters first discovered the alleged defect in her clip. See [D.E. 23] 19. In support, Watters notes that UTMD's marketing materials for their clips since 2019 "were likely one of the reasons why Plaintiff, her doctors and her healthcare teams were unaware of the Filshie Clips'

propensity to migrate." Id. at 20. However, it was not UTMD's advertising that caused Watters's alleged injury, but a clip developed by a completely different company. Watters's argument also ignores Supreme Court precedent interpreting when a defendant's activities"arise or relate" to the litigation for purposes of personal jurisdiction. See, e.g., Bristol-Myers Squibb, 137 S. Ct. at 1780; Burger King, 471 U.S. at 472–73.

Next, Watters asks this court to follow Bulox v. CooperSurgical, Inc., No. CV 21-2320, 2022 WL 2132680 (S.D. Tex. June 14, 2022) (unpublished). See [D.E. 23] 20–21. In Bulox, the court held that it had personal jurisdiction over UTMD due to UTMD's business operations in Texas. See Bulox, 2022 WL 2132680, at *2.

Bulox does not help Watters. In Bulox UTMD and TCC failed to argue in their initial motion to dismiss that UTMD and TCC did not operate in Texas during the time of plaintiffs' surgery. See id., Order, [D.E. 65]. The Bulox court denied defendants' motion to reconsider because defendants failed to argue in their initial motion to dismiss that UTMD and TCC were not market participants in Texas when plaintiff underwent surgery. Id. Unlike in Bulox, UTMD and TCC did not waive their argument in this case.

In contrast to Bulox, Froman v. Coopersurgical, Inc., No. 2:22-cv-00110, 2022 WL 2657117 (N.D. Ala. July 8, 2022) (unpublished), supports defendants' argument. In Froman, the same defendants as in this case also moved to dismiss for lack of personal jurisdiction and made the same arguments. See id. at *3. The district court in Froman agreed with the defendants and rejected the theory that "when a company begins marketing and distributing a product in a particular forum, it automatically subjects itself to personal jurisdiction for any suit relating to an identical product made

by a competitor in that forum." Id.[1]

As for TCC, Watters does not appear to dispute that TCC lacks sufficient minimum contacts with North Carolina. [D.E. 23] 23–27. In fact, Watters does not respond to defendants' arguments about TCC. But even if Watters made the same arguments about TCC as she did about UTMD, the arguments would fail for the same reasons.

As for Femcare, Watters argues that because Femcare sold clips in 2013 to CSI and CSI in turn sold the clips in North Carolina, then Femcare has sufficient minimum contacts in North Carolina for personal jurisdiction. See [D.E. 31] 18. Essentially, Watters argues that because Femcare entered into a contract with a distributor allowing the sale of Femcare's products in the entire United States, then Femcare is subject to personal jurisdiction in every state in the United States where such clips were sold. See id. at 21–23.

The Fourth Circuit has expressly rejected Watters's stream of commerce theory, instead holding that "a non-resident defendant may only be subject to personal jurisdiction under the 'stream of commerce theory' if that defendant engaged in some activity purposely directed at the forum state." In re Celotex Corp., 124 F.3d 619, 629 (4th Cir. 1997); see, e.g., Lesnick v. Hollingsworth & Vose Co., 35 F.3d 939, 945 (4th Cir. 1994); Smith v. Teledyne Cont'l Motors, Inc., 840 F. Supp. 2d 927, 931–32 (D.S.C. 2012). For example, a court may find that a manufacturer purposely directed activity towards a forum state when the manufacturer sells finished products directly to retail stores that the manufacturer knows or should know have locations in the forum state. See

[1] On January 18, 2023, Watters filed a notice of "suggestion of subsequently decided authority" and attached Blevins-Ellington v. Utah Medical Products, Inc., No. 1:22-CV-197 (N.D. Ga. Jan. 18, 2023) (unpublished), Order, [D.E. 66]. See [D.E. 32, 32-1]. The court has reviewed plaintiffs' notice and the attached order from Blevins-Ellington. The court finds Blevins-Ellington distinguishable on the issue of personal jurisdiction. See, e.g., [D.E. 34] 7 n.4.

Estes v. Midwest Prods., Inc., 24 F. Supp. 2d 621, 630–32 (S.D.W. Va. 1998) (noting that the defendant-manufacturer had a direct purpose to have its finished products sold in Kmart and Wal-Mart stores in West Virginia and as such "the defendant structures its primary conduct with genuine assurance that its activities will render them liable to suit in West Virginia"). In contrast, a defendant-manufacturer who sells a product to a distributor with no direct purpose that the product reach the forum state is not subject to personal jurisdiction even if the defendant is abstractly aware that a distributor could sell its product in the forum state. See Jeffers v. Wal-Mart Stores, Inc., 152 F. Supp. 2d 913, 921 (S.D.W. Va. 2001).

Femcare did not sell their clips to CSI with the direct purpose that CSI resell these clips in North Carolina. Instead, as plaintiffs admit, Femcare did not intend that its distribution through CSI would specifically target the North Carolina market. See [D.E. 31] 22–23. Moreover, CSI controlled the decision to sell the clips to North Carolina consumers and the details of those transactions (such as, to whom the clips would be sold, the volume of clips sold, and the price). See [D.E. 31-4] 13. Therefore, the court lacks personal jurisdiction over Femcare.

In opposition, Watters argues that Femcare exercised significant contractual control over how CSI packaged and marketed the clips and that this contractual control established minimum contacts with North Carolina. See [D.E. 31] 20–21. Watters, however, has not plausibly alleged that CSI and Femcare were so intertwined as to make CSI the alter ego of Femcare.

Watters also cites two distinguishable patent cases. See Hanamint Corp. v. Alliant Mktg. Grp., LLC, 481 F. Supp. 2d 444, 446 (M.D.N.C. 2007); Akeva LLC v. Mizuno Corp., 199 F. Supp. 2d 336, 338 (M.D.N.C. 2002). In those patent cases, however, the courts were applying the personal jurisdiction jurisprudence of the United States Court of Appeals for the Federal Circuit.

The court does not have personal jurisdiction over TCC, UTMD, or Femcare. Thus, the court grants these defendants' motion to dismiss for lack of personal jurisdiction.

IV.

CSI, TCC, UTMD, and Femcare also move to dismiss for failure to state a claim. A motion to dismiss under Rule 12(b)(6) tests the complaint's legal and factual sufficiency. See Ashcroft v. Iqbal, 556 U.S. 662, 677–80 (2009); Bell Atl. Corp. v. Twombly, 550 U.S. 544, 554–63 (2007); Coleman v. Md. Court of Appeals, 626 F.3d 187, 190 (4th Cir. 2010), aff'd, 566 U.S. 30 (2012); Giarratano v. Johnson, 521 F.3d 298, 302 (4th Cir. 2008). To withstand a Rule 12(b)(6) motion, a pleading "must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." Iqbal, 556 U.S. at 678 (quotation omitted); see Twombly, 550 U.S. at 570; Giarratano, 521 F.3d at 302. In considering the motion, the court must construe the facts and reasonable inferences "in the light most favorable to the [nonmoving party]." Massey v. Ojaniit, 759 F.3d 343, 352 (4th Cir. 2014) (quotation omitted); see Clatterbuck v. City of Charlottesville, 708 F.3d 549, 557 (4th Cir. 2013), abrogated on other grounds by Reed v. Town of Gilbert, 576 U.S. 155 (2015). A court need not accept as true a complaint's legal conclusions, "unwarranted inferences, unreasonable conclusions, or arguments." Giarratano, 521 F.3d at 302 (quotation omitted); see Iqbal, 556 U.S. at 678–79. Rather, a plaintiff's factual allegations must "nudge[ ] [her] claims," Twombly, 550 U.S. at 570, beyond the realm of "mere possibility" into "plausibility." Iqbal, 556 U.S. at 678–79.

When evaluating a motion to dismiss, a court considers the pleadings and any materials "attached or incorporated into the complaint." E.I. du Pont de Nemours & Co. v. Kolon Indus., Inc., 637 F.3d 435, 448 (4th Cir. 2011); see Fed. R. Civ. P. 10(c); Goines v. Valley Cmty. Servs. Bd., 822 F.3d 159, 166 (4th Cir. 2016); Thompson v. Greene, 427 F.3d 263, 268 (4th Cir. 2005). A court may

also consider a document submitted by a moving party if it is "integral to the complaint and there is no dispute about the document's authenticity." Goines, 822 F.3d at 166. Additionally, a court may take judicial notice of public records without converting the motion to dismiss into a motion for summary judgment. See, e.g., Fed. R. Evid. 201; Tellabs, Inc. v. Makor Issues & Rts., Ltd., 551 U.S. 308, 322 (2007); Philips v. Pitt Cnty. Mem'l Hosp., 572 F.3d 176, 180 (4th Cir. 2009).

CSI, TCC, UTMD, and Femcare argue that Watters's state-law claims are preempted. See [D.E. 19] 9; [D.E. 26] 2. In support, they note that the Medical Device Amendments of 1976 ("MDA") to the Food, Drug, and Cosmetic Act "provides a rigorous, comprehensive, and exclusive framework that precludes state law tort claims that seek to impose different or higher standards upon federally approved devices." Walker v. Medtronic, Inc., 670 F.3d 569, 578 (4th Cir. 2012). The MDA covers implantable medical devices that receive "premarket approval" by the FDA, such as the clips in this case. Id. at 574, 577.

"The premarket approval process includes review of the device's proposed labeling." Riegel v. Medtronic, Inc., 552 U.S. 312, 318 (2008). "Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." Id. at 319. "If the applicant wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental premarket approval, to be evaluated under largely the same criteria as an initial application." Id. "After premarket approval, the devices are subject to reporting requirements," including "to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred." Id.

The MDA preempts state law claims in two ways. "First, the MDA expressly preempts any state law 'requirement . . . which is different from, or in addition to, any requirement applicable under [the MDA] to the device.'" McNeil-Williams v. DePuy Orthopaedics, Inc., 384 F. Supp. 3d 570, 574 (E.D.N.C. 2019) (quoting 21 U.S.C. § 360k(a)(1)) (alteration in original). Notably, "common-law causes of action for negligence and strict liability . . . impose 'requirements' and would be pre-empted by federal requirements specific to a medical device." Riegel, 552 U.S. at 323–24 (alteration omitted). Accordingly, "[s]tate requirements are pre-empted under the MDA only to the extent that they are different from, or in addition to the requirements imposed by federal law." Id. at 330 (quotation omitted). The MDA does not expressly preempt state law claims based upon "state duties [that] . . . parallel, rather than add to, federal requirements." Id. (quotations omitted).

Second, the MDA implicitly preempts additional types of state law claims. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 350–53 (2001). The MDA "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions[.]" Id. at 349 n.4; 21 U.S.C. § 337(a). Causes of action not arising from "traditional state tort law which . . . predated the federal enactments in question" are preempted. Id. at 353. Specifically, actions arising "solely from the violation of [MDA] requirements," are implicitly preempted because "Congress intended that the MDA be enforced exclusively by the Federal Government." Id. at 352.

"These two types of preemption, operating in tandem, have created . . . a 'narrow gap' for pleadings" in a medical device products liability case. Mink v. Smith & Nephew, Inc., 860 F.3d 1319, 1327 (11th Cir. 2017); McNeil-Williams, 384 F. Supp. 3d at 574. "To make it through, a plaintiff has to sue for conduct that violates a federal requirement (avoiding express preemption), but cannot sue only because the conduct violated that federal requirement (avoiding implied

preemption)." Mink, 860 F.3d at 1327.

Every state-law claim in Watters's complaint alleges breaches of a duty that "parallels the FDCA's requirement for truthfully and completely reporting incidents of adverse events, and if necessary, obtaining approval for changes in the design, manufacture, and warnings/marketing approved by the FDA." Compl. ¶ 94 (claim 2); ¶ 102 (claim 3); ¶ 122 (claim 4); and ¶ 132 (claim 5). Although Watters's first claim does not use this "parallel" duty language, Watters does allege that defendants failed to honestly and actively report data regarding clip migration to the FDA as required. Id. at ¶ 82 ("Further, the increased incidence of migration reported since 1996 was not reported to the FDA, despite Defendants' knowledge of the same; a continued duty and requirement after obtaining the PMA. Such failure allowed for the defective design to remain the same.").

"North Carolina law does not recognize a parallel duty on manufacturers to report to the FDA[.]" McNeil-Williams, 384 F. Supp. 3d at 575. Additionally, Watters's state law claims assert a "fraud-on-the-FDA" theory that the Supreme Court in Buckman explicitly held were preempted by the MDA. See Buckman, 531 U.S. at 350. Watters's complaint and arguments are also strikingly similar to those made in Froman. See Froman, 2022 WL 2657117, at *5–7. The court in Froman held that plaintiffs' use of the "parallel" duty language in the complaint was "squarely barred by the MDA's implied preemption provision." Id. at *6.

Watters insists that she is not making fraud-on-the FDA claims. See [D.E. 23] 12–13. Watters, however, admits that she "seeks a [jury] finding that the FDA would have made different decisions if Defendants reported the true risk of migration to the FDA. Defendants deprived the FDA a chance to do its job of protecting the public from this device." Id. at 11. Thus, Watters is pursuing fraud-on-the-FDA claims under state law. Id. Under Buckman, Watters's claims are preempted. See Buckman, 531 U.S. at 350.

In opposition, Watters argues that her complaint simply uses examples of defendants' alleged breaches of duties to the FDA as a "measure of the standard of care and as evidence of wrongdoing, to support their [sic] state law claims." [D.E. 23] 13. If so, however, the MDA expressly preempts Watters's claims. See Buckman, 531 U.S. at 350. Moreover, claiming that defendants owed a duty to Watters or her doctors functions to "impose [additional] requirements and would be pre-empted by federal requirements specific to a medical device." Riegel, 552 U.S. at 323–24. Although Watters alleges that her state law claims run "parallel" to a duty owed to the FDA under federal regulations, Watters never explicitly identifies which regulations. See generally [D.E. 1]. Indeed, Watters admits that she has failed to plead specific violations of the FDA regulations but requests limited discovery to uncover the regulations that potentially could apply. [D.E. 23] 11–12.

In support of limited discovery, Watters cites Brumfield v. Medtronic, Inc., No. CV 3:20-0522, 2021 WL 933869, at *6 (S.D.W. Va. Mar. 11, 2021) (unpublished), for the proposition that she need not cite a specific federal regulation to survive a motion to dismiss. See [D.E. 23] 11. The plaintiff in Brumfield included in his complaint redacted "warning letters" from the FDA regarding potential manufacturing defects in defendants' motors and the likelihood that these defects could injure consumers. Brumfield, 2021 WL 933869, at *6.

Unlike in this case, the defendants in Brumfield were the only ones who had access to the unredacted FDA letters, and the plaintiff in Brumfield was able to directly link the malfunction of his specific device specifically to the malfunctions the FDA warned about in the letters. Id. Moreover, unlike in Brumfield, Watters fails to cite specific evidence only possessed by the defendants which could reveal the precise federal regulation defendants allegedly violated in this case. The court declines to conscript defendants to find regulations for Watters to plead on her own behalf. See Ind. Coal Council v. Hodel, 118 F.R.D. 264, 266 (D.D.C. 1988). The court also declines

to hunt for FDA regulations which potentially could fit her case. See Hensley ex rel. N.C. v. Price, 876 F.3d 573, 580–81 n.5 (4th Cir. 2017).

Next, Watters cites Godelia v. Doe 1, 881 F.3d 1309, 1319 (11th Cir. 2018). See [D.E. 23] 10. In Godelia the plaintiff explicitly alleged that a violation of 21 CFR § 820.198(a) resulted in wrongful death. See Godelia, 881 F.3d at 1319. In contrast, Watters has failed to allege a violation of a specific federal regulation or particular deviation from the FDA-approved process. See, e.g., Weber v. Allergan, Inc., 940 F.3d 1106, 1112 (9th Cir. 2019); Wolicki-Gables v. Arrow Int'l, Inc., 634 F.3d 1296, 1301 (11th Cir. 2011); Diodato v. Mentor Worldwide, LLC, No. CV 20-761, 2020 WL 3402296, at *2 (D. Md. June 19, 2020) (unpublished); Parker v. Stryker Corp., 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008). Thus, Godelia provides no help.

Finally, Watters cites the preemption analysis in Blevins-Ellington. The court, however, respectfully rejects as unpersuasive the preemption analysis in Blevins-Ellington.

V.

In sum, the court GRANTS moving defendants' motion to dismiss [D.E. 18, 25] and DISMISSES WITHOUT PREJUDICE the complaint. Watters must file any amended complaint not later than March 6, 2023.

SO ORDERED. This 13 day of February, 2023.

JAMES C. DEVER III
United States District Judge